

## **REMARKS**

### **Disposition of the Claims**

This response is intended to be a full and complete response to the non-final Office Action mailed May 21, 2008. In view of the rejections contained in the Office Action, claims 16 to 30 have been cancelled and rewritten as newly added claims 31 to 53. Accordingly, newly added claims 31 to 53 are pending in the present application.

Applicants respectfully thank the Examiner for the acknowledgement of the claim to priority and the review of the Information Disclosure Statement. Applicants respectfully request continued examination of the present application and allowance of the pending claims.

### **Amendments to the Specification**

In the Office Action, the Examiner reminded Applicants of the proper sections to be included in the specification. Applicants respectfully note that in the present response, Applicants include amendments addressing these sections as well as the inclusion of a Brief Description of the Figures. Applicants respectfully request entry of these amendments.

### **35 U.S.C. § 101 and 35 U.S.C. § 112, Second Paragraph, Rejections**

In the Office Action, the Examiner rejected claims 16 to 25 under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims as defined in 35 U.S.C. § 101. In addition, the Examiner also rejected claims 16 to 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner notes that "a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how the use is actually practiced."

These rejections are respectfully traversed with regard to newly added claims 31 to 53.

Applicants note that claims 16 to 25, along with claims 26 to 30, have been cancelled. Claims 16 to 30 have been redrafted and are now resubmitted as newly added claims 31 to 42 which are directed to a process for preventing or treating a neurointoxication in a human patient, claims 43 to 49 which are directed to a gaseous inhalable medicament for the treatment of addiction, claims 50 to 52 which are directed to a process for treating addiction and finally claim 53 which is directed to a process for the manufacture of a medicament. Applicants maintain that these new claims meet the requirements of 35 U.S.C. § 101 and 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 101 and 35 U.S.C. § 112, second paragraph, rejections.

#### **Second 35 U.S.C. § 112, Second Paragraph, Rejection**

The Examiner also rejected claim 30 under 35 U.S.C. § 112, second paragraph, on the basis that the claim recites a broad recitation followed by a narrower recitation.

Applicants note that claim 30 has been cancelled and rewritten as newly added claim 47. When this claim was rewritten, the more narrow range was removed and included as newly added claim 49 which depends from newly added claim 47. In view of these amendments, Applicants respectfully submit that this rejection has been made moot and respectfully request withdrawal of the rejection.

#### **First 35 U.S.C. § 102(a) Rejection**

The Examiner rejected claims 26, 27, 29 and 30 under 35 U.S.C. 102(a) as being anticipated by Homi, et al, Anesthesiology 2003, 99, pgs. 876-881 (hereinafter "Homi"). This rejection is respectfully traversed with regard to newly added claims 43, 44, 46, 47, 48, and 49.

Applicants respectfully maintain that the priority date for the instant application predates Homi and in view of this, Homi should not be considered as prior art with regard to the present application. More specifically, the publication date of Homi is October 2003. With regard to the present application, Applicants reference the PCT application from which this national application claims priority and note that the PCT application was filed on July 23, 2004 and claims priority to French Patent Application 03/50383 which was filed on July 30, 2003—prior to the publication date of Homi. In view of this, Applicants respectfully request reconsideration of these dates by the Examiner and withdrawal of this rejection.

#### **Second 35 U.S.C. § 102(a) Rejection**

The Examiner also rejected claims 26, 27 and 30 under 35 U.S.C. 102(a) as being anticipated by Mondain-Monval, U.S. Patent No. 4,820,258 (hereinafter “Mondain-Monval”). This rejection is respectfully traversed with regard to newly added claims 43, 44, 47, 48, and 49.

Applicants maintain that claims 43, 44, 47, 48, and 49 are not anticipated by Mondain-Monval since Mondain-Monval fails to disclose a gaseous inhaled medicament for the treatment of addiction.

The Examiner indicated that Mondain-Monval discloses gaseous mixtures containing from about 50 to 80% by volume nitrous oxide; at least about 20% by volume oxygen and an inert gas; xenon (claims 1-5). Thus, according to the Examiner, the disclosure of Mondain-Monval embraces a gaseous mixture of 50% by volume nitrous oxide; 20% by volume oxygen and 30% by volume xenon or 50% nitrous oxide; 30% oxygen and 20% xenon and therefore anticipates claims 26, 27 and 30.

Applicants respectfully disagree with the Examiner. While Mondain-Monval do disclose a mixture of oxygen, xenon and nitrous oxide, the mixture utilized by Mondain-Monval is for a completely different purpose as clearly set forth in Mondain-Monval. More specifically, Mondain-Monval's invention is a method for delivering radiation to target tissue of a patient undergoing cancer radiotherapy using a gaseous mixture that has at least 50% by volume of nitrous oxide. Mondain-Monval further provide that the mixture can have at least 20% by volume of oxygen and also an inert gas selected from nitrogen, argon, krypton, xenon and helium.

There is no indication in Mondain-Monval that the gas mixture of Mondain-Monval can be used for the treatment of addiction. In addition, with regard to claim 43, there is no indication in Mondain-Monval that the mixture could be xenon and nitrous oxide. In the embodiments of Mondain-Monval where xenon is included, it is clearly stated that this is in "...a ternary mixture consisting of oxygen, nitrous oxide and the complement to 100 by volume by an inert gas selected from nitrogen, argon, krypton, xenon and helium." See column 2, lines 10-14.

In view of the above, Applicants maintain that claims 43, 44, 47, 48, and 49 are clearly patentable over Mondain-Monval. Accordingly, Applicant respectfully requests withdrawal of the rejection of said claims under 35 U.S.C. § 102(a) as being anticipated by Mondain-Monval.

### **First 35 U.S.C. § 103 Rejection**

The Examiner rejected claims 26 to 30 under 35 U.S.C. § 103(a) as being unpatentable over Petzelt, et al, WO 00/53192 (hereinafter "Petzelt") in view of David, et al, reference C3 on the IDS submitted on 10/06/06 (hereinafter "David") and Jevtovic-Todorovic, et al, reference C7 on the IDS submitted on 10/06/06 (hereinafter "Jevtovic-Todorovic") and Homi. This rejection is respectfully traversed with regard to newly added claims 43 to 49.

Claims 43 to 49 are patentable over Petzelt in view of David, Jevtovic-Todorovic and Homi since these references, whether considered alone or in combination fail to teach or suggest a gaseous inhalable medicament for preventing or treating addiction that comprises from 5% to 35% by volume of xenon and from 10% to 50% by volume of nitrous oxide in one embodiment and a further embodiment that contains oxygen.

In the Office Action, the Examiner stated that Petzelt does not expressly teach a composition with 20-40% nitrous oxide or a composition of xenon and nitrous oxide of about 30%. The Examiner indicated that the deficiency of Petzelt is cured by the teachings of Homi, Jevtovic-Todorovic and David. Applicants respectfully disagree.

First, Applicants refer to the above-noted discussion regarding Homi and the position held by Applicants that the present application, taking into consideration the priority claimed, predates Homi. Accordingly, Applicants respectfully request reconsideration of these dates by the Examiner and withdrawal of Homi as a reference in this rejection.

Petzelt discloses the use of xenon or xenon mixed with either oxygen or air for treating neurointoxication. Petzelt fails to discuss the use of other gases such as nitrous oxide in combination with xenon and oxygen. Furthermore, Petzelt fails to indicate that the gaseous mixture can be used for the prevention or treatment of addiction.

Jevtovic-Todorovic does discuss nitrous oxide with regard to anesthesia (the article suggests that nitrous oxide could possibly be used as an anesthetic in certain situations such as cardiac bypass surgery since it may provide neuroprotection against cerebral ischemic events that sometimes accompany such surgery) but goes

on to point out in the first paragraph of the reference that nitrous oxide is also a “drug of abuse”.

David discloses the use of nitrous oxide and xenon in treating cerebral stroke or other brain pathologies that involve excitotoxicity.

In view of the above, Applicants maintain that one skilled in the art, considering the references cited by the Examiner would not be led to utilize a gaseous inhaled medicament that contains nitrous oxide (and xenon and oxygen) for the prevention or treatment of addiction, especially drug addiction, since one skilled in the art would not likely utilize a component to treat or prevent “addiction” that (1) has the potential for abuse or (2) is used to treat strokes.

In view of the above, Applicants maintain that claims 43 to 49 are patentable over Petzelt in view of David, Jevtovic-Todorovic and Homi and respectively request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

### **Second 35 U.S.C. § 103 Rejection**

The Examiner rejected claims 26 to 30 under 35 U.S.C. § 103(a) as being unpatentable over Petzelt in view of Jevtovic-Todorovic. This rejection is respectfully traversed with regard to newly added claims 43 to 49.

Claims 43 to 49 are patentable over Petzelt in view of Jevtovic-Todorovic since these references, whether considered alone or in combination fail to teach or suggest a gaseous inhalable medicament for preventing or treating addiction that comprises from 5% to 35% by volume of xenon and from 10% to 50% by volume of nitrous oxide in one embodiment and a further embodiment that contains oxygen.

In the Office Action, the Examiner stated that Petzelt does not expressly teach a composition with 20-40% nitrous oxide or a composition of xenon and nitrous oxide of about 30%. The Examiner indicated that the deficiency of Petzelt is cured by Jevtovic-Todorovic. Applicants respectfully disagree.

Petzelt discloses the use of xenon or xenon mixed with either oxygen or air for treating neurointoxication. Petzelt fails to discuss the use of other gases such as nitrous oxide in combination with xenon and oxygen. Furthermore, Petzelt fails to indicate that the gaseous mixture can be used for the prevention or treatment of addiction.

The secondary reference cited by the Examiner, Jevtovic-Todorovic fails to overcome the deficiencies of Petzelt. While Jevtovic-Todorovic does discuss nitrous oxide with regard to anesthesia (the article suggests that nitrous oxide could possibly be used as an anesthetic in certain situations such as cardiac bypass surgery since it may provide neuroprotection against cerebral ischemic events that sometimes accompany such surgery), Jevtovic-Todorovic points out in the first paragraph that nitrous oxide is also a "drug of abuse".

In view of the above, Applicants maintain that one skilled in the art, considering Petzelt in view of Jevtovic-Todorovic, would not be led to utilize a gaseous inhaled medicament that contains nitrous oxide (and xenon and oxygen) for the prevention or treatment of addiction since one skilled in the art would not likely utilize a component that has the potential for abuse to treat "addiction".

In view of the above, Applicants maintain that claims 43 to 49 are patentable over Petzelt in view of Jevtovic-Todorovic and respectively request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

### **Additional Comments**

Before closing, the Examiner noted that there is a potential for a double patenting rejection once the claims have been amended. However, since the Examiner only noted that there is a "potential", Applicants have not addressed this issue at this point.


### **CONCLUSION**

Accordingly, it is believed that the present application now stands in condition for allowance. Early notice to this effect is earnestly solicited. Should the Examiner believe a telephone call would expedite the prosecution of the application, the Examiner is invited to call the undersigned attorney at the number listed below.

Due to the addition of new claims, Applicants herewith submit the necessary fees for the addition of these claims. It is not believed that any other fee is due at this time. If this belief is incorrect, please debit deposit account number 01-1375. Also, the Commissioner is authorized to credit any overpayment to deposit account number 01-1375.

Respectfully submitted,

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